510(k) Summary

510(k) Number: K131177

Device Name: SinuFlush Lavage System

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter's Name and Address

HedgePath, LLC
Suite 350
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Tampa, FL 33606

Contact: Frank E. O'Donnell, Jr MD.
Acting Director of Regulatory Affairs
(314) 258-6446
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Device Name

Trade Name:	SinuFlush Lavage System
Common Name:	Ear, nose, and throat manual surgical instrument
Classification Name:	Ear, nose, and throat manual surgical instrument (21 CFR 874.4420)
Product Code:	KAR

Predicate Device

	New Device	Predicate
Device Name	SinuFlush Lavage System	Sinusense Nasal Rinse
Manufacturer	HedgePath, LLC	Water Pik, Inc.
Regulation Number/ Product Code	874.4420, KAR (Proposed)	874.4420, KAR (Exempt)
Indication for Use	The SinuFlush Lavage System is intended for nasal and sinus irrigation in patients who are under the care of a physician. The SinuFlush Lavage System is a prescription use product that is to be used by adults in either the physician's office or in the home after obtaining instructions from a health care provider.	Sinusense Nasal Rinse: "Sinus wash has been used for centuries as a natural daily routine to keep sinus passages clear of congestion, allergens and everyday debris. It's an all-natural approach to better breathing that makes perfect sense when you consider all of the other remedies on the market. The Waterpik® SinuSenseTM Sinus Wash products and the uniquely formulated Soothing Saline Easy- Pour Packs clear sinuses to make breathing easier."
Principle of Operation	Irrigant is delivered by pushing the plunger of the 25 cc syringe under the manual control of the patient.	Irrigant is delivered by manual pressure by the user.
Nase contact mechanism	The nase is occluded by be specifically designed silicon tip.	The nase is occluded by a specifically designed non-rubber, non-latex tip.

Device Description

The SinuFlush Lavage System is a hand held 25 cc syringe with a plunger to control the force of delivery and volume markings on its side in order to measure the amount of irrigant to be delivered. The tip consists of soft silicone to occlude the nasal ostium during irrigation. The mixing container consists of a 25 cc container with markings on its side for volume measurement in cc, and a plastic screw top to secure the contents of the container during shaking.

The SinuFlush Lavage System is substantially equivalent to the Sinusense Nasal Rinse.

Intended Use

The SinuFlush Lavage System is intended for nasal and sinus irrigation in patients who are under the care of a physician. The SinuFlush Lavage System is a prescription use product that is to be used by adults in either the physician's office or in the home after obtaining instructions from a health care provider.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

HedgePath, LLC
c/o Frank E. O'Donnell, Jr., M.D.
Acting Director of Regulatory Affairs
324 S. Hyde Park Avenue, Suite 350
Tampa, FL 33606

Re: K131177
Trade/Device Name: SinuFlush Lavage System
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, and Throat Manual Surgical Instrument
Regulatory Class: Class 1
Product Code: KAR
Dated: August 7, 2013
Received: August 8, 2013

Dear Dr. O'Donell:

This letter corrects our substantially equivalent letter of September 20, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form (Text Version)

Indications for Use

510(k) Number (if known): K131177

Device Name: SinuFlush Lavage System

Indications for Use:

The SinuFlush Lavage System is intended for nasal and sinus irrigation in patients who are under the care of a physician. The SinuFlush Lavage System is a prescription use product that is to be used by adults in either the physician's office or in the home after obtaining instructions from a health care provider.

Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vasant G. Malshet

Digitally signed by Vasant G. Malshet
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Vasant G. Malshet, 0.9.2342.19200300.100.1.1=1300087851
Date: 2013.09.19 10:23:31 -04'00'